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United States District Court,S.D. California.
IDEC PHARMACEUTICALS, Plaintiff
v.
CORIXA CORPORATION, et al., Defendants.
CORIXA CORPORATION, et al., Counterclaimants
v.
IDEC PHARMACEUTICALS CORP., Counterdefendant.
No. 01-1637-IEG(RBB).

Oct. 14, 2003.

F. T. Alexandra Mahaney, Wilson, Sonsini, Goodrich and Rosati, and Jessica R. Wolff, Paul, Hastings, Janofsky and Walker, San Diego, CA, for Plaintiff.
William G. Gaede, III, Cooley, Godward, Palo Alto, CA, for Defendants.
William G. Gaede, III, Cooley, Godward, Palo Alto, CA; Martin I. Fuchs, Finnegan, Henderson, Farabow, Washington, DC; and Donald G. Rez, Sullivan, Hill, Lewin, Rez, San Diego, CA, for Counterclaimants.
F. T. Alexandra Mahaney, Wilson, Sonsini, Goodrich and Rosati, San Diego, CA, for Counterdefendant.

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DENYING AS MOOT PLAINTIFF'S MOTION TO STRIKE
GONZALEZ, J.

[Doc. Nos. 486, 584]

***1** Presently before the Court is plaintiff IDEC Pharmaceuticals Corporation's ("IDEC") motion for summary judgment of unenforceability of four U.S. patents due to inequitable conduct. Additionally, IDEC requests in its reply that the Court strike certain evidence filed by defendants Corixa Corporation, Coulter Pharmaceutical, Inc., the Regents of the University of Michigan and counterclaimant Smithkline Beecham Corporation (collectively, "defendants") in opposition to IDEC's motion. (*See* IDEC's Mot. to Strike Decls. of Kaminski and Wahl). Having considered the parties' briefs and having heard oral argument, the Court grants the motion for summary judgment, and denies the motion to strike.

BACKGROUND

IDEC filed a complaint for a declaratory judgment of non-infringement and invalidity of U.S. Patent numbers 5,595,721 (the '721 patent), 6,015,542 (the '542 patent), 6,090,365 (the '365 patent), and 6,287,537 (the '537 patent) (collectively the "patents at issue") against defendants. On February 13, 2002, defendants filed a counterclaim for patent infringement on the '721, '542, and '365 patents. Defendants subsequently amended their counterclaim to include a claim for patent infringement on the '537 patent. Following extensive briefing and argument on claim construction, the Court issued an Order on May 28, 2003 construing the patent claims.

On August 13, 2003 IDEC filed the present motion for summary judgment alleging that the patents at issue are invalid due to inequitable conduct on the part of the inventors, Drs. Kaminski, Butchko, Glenn and Wahl (collectively, the "patentees"). Defendants filed an opposition to the motion on September 5, 2003, and IDEC filed a timely reply to the opposition.

The Court finds the following material facts to be undisputed.

A. The Underlying Technology

This case and the patents at issue involve a method of treating non-Hodgkin's lymphoma, also called B-cell lymphoma. B-cell lymphoma is a cancer of the immune system, and it is the fifth leading cause of cancer-related deaths in the United States. The patented treatment employs radioimmunotherapy ("RIT") to deliver radiation to malignant cells in the lymphatic system. RIT involves attaching a radioactive isotope [FN1] (a radiolabel) to an antibody or antibody fragment [FN2] that has a natural affinity to these malignant cells. More specifically, the antibody targets a molecule called an antigen. Apparently, there is a group of "pan B-cell antigens" which include CD37 and CD20, the antigens at issue in the present case.[FN3] The patents at issue employ an "anti-CD20 antibody" called B1, while the prior art cited by IDEC used an "anti-CD37 antibody" called MB1.[FN4] Once the antibody (either B1 or MB1) attaches to a cell on a B-cell lymphoma tumor, the ^{131}I radiolabel emits radiation that is designed to

destroy not only the cell to which the antibody is attached, but also the surrounding cells.

FN1. The patented method as well as the prior art cited by IDEC use an Iodine 131 (^{131}I) radiolabel.

FN2. An antibody is a protein, also known as an immunoglobulin. Each antibody has a unique amino acid sequence that defines its ability to react with the antigen epitope to which it binds.

FN3. "CD" in the name of the antigen refers to the term "clusters of differentiation." This term refers to antigens recognized by multiple, different antibodies.

FN4. An anti-CD20 or anti-CD37 antibody refers to an antibody that binds to the CD20 or CD37 antigen, respectively. Thus, the patents at issue use the B1 (anti-CD20) antibody, which binds to the CD20 antigen, while the prior art cited by IDEC used the MB1 (anti-CD37) antibody, which binds to the CD37 antigen.

An important aspect of the methods described by the patents at issue is that the radiation dose delivered to the patient through RIT is less than that which would necessitate autologous bone marrow transplant (ABMT).[FN5] This is apparently a significant advance in the treatment of cancer, since many prior radiation therapies were only successful when enough radiation was delivered to the patient to require such a potentially fatal transplant.

FN5. In the language of the claims, this is phrased as "radioactivity ... less than that which causes myelosuppression severe enough to require the reintroduction of hematopoietic stem cells into the patient in order for the patient to recover hematopoietic function." *See e.g.,* claim 27 of the '537 patent. A dose of RIT radiation not requiring ABMT is also referred to as a "non-myeloablative dose."

*2 Another distinguishing feature of the patented methods are that most of them involve both "imaging" and "therapy" steps. Patients are first administered a dose of radiolabeled antibodies calculated to allow an image to be made of the distribution of B-cells in the body. Following this imaging step, patients are given another dose of radiolabeled antibodies intended to destroy the B-cell lymphomas. In both of these steps, the methods involve the administration of a "cold" dose of antibodies-antibodies without a radiolabel-to block the binding sites on healthy B-cells, thus reserving the binding sites on the cancerous B-cells for the "hot," radiolabeled antibodies. [FN6]

FN6. The administration of the "cold" dose is referred to as "pre-dosing."

B. The MB1 Prior Art

In November of 1986, IDEC filed an Investigational New Drug Application (IND) that involved conducting clinical trials to determine the effectiveness of treating B-cell lymphomas with ^{131}I-MB1.[FN7] The principle investigator named in this protocol (the "MB1 protocol") was Dr. Kaminski (one of the named inventors in the patents at issue). (*See* IDEC Ex. 11 at 0107738). Among the associate investigators named in the MB1 protocol were Dr. Wahl (also a named inventor in the patents at issue) and Dr. Miller of IDEC (who is not named as an inventor in any of the patents at issue). (*Id.*). The MB1 protocol called for administering small doses of ^{131}I, and escalating slowly, "to avoid possible excessive bone marrow toxicity and other possible toxicities." (*Id.* at 0107746, ¶ 6.97).

FN7. ^{131}I-MB1 refers to an MB1 antibody (which would bind to the CD37 antigen) labeled with the ^{131}I radiolabel.

In 1990, Drs. Kaminski, Wahl, Miller and others published at least five abstracts in which they described the treatment of various B-cell lymphoma patient groups with ^{131}I-MB1. The first of these abstracts, ("Abstract # 83") involved a study of five patients with B-cell lymphoma. The abstract stated that in order to "assess the efficacy of [RIT] of advanced B-cell lymphomas we have been conducting a radioactivity dose escalation study using doses of the ^{131}I labeled MB1 monoclonal antibody not expected to require bone marrow transplantation support." (IDEC Ex. 5). After discussing the results of the ^{131}I-MB1 treatment in the five patients, the authors concluded that the "dose-escalation trial demonstrates that significant tumor responses can be induced at nonmyelosuppressive doses [not requiring ABMT] of ^{131}I-MB1 in patients

with large tumor burdens." (*Id.*).

The second 1990 abstract ("Abstract # 1051") discussed another group of patients treated with ^{131}I-MB1. In this abstract, the authors indicate that some patients, who were treated with higher doses of radiation and had been heavily pre-treated with radiation therapies, suffered from myelosuppression. (*See* IDEC Ex. 6). Nonetheless, various patients achieved tumor responses without ABMT-inducing doses of ^{131}I. (*Id.*). This led the authors of Abstract # 1051 to conclude that "^{131}I-MB1 can be used for [RIT] and has significant anti-tumor activity in [patients] with large tumor burdens at nonmyolosuppressive doses and at doses below those requiring bone marrow transplant support." (*Id.*).

***3** A third abstract ("Abstract # 622") summarized the results from six patients treated with ^{131}I-MB1. (*See* IDEC Ex. 7). Again, the authors concluded that "^{131}I-MB1 can be used for [RIT] of B-cell lymphoma and beneficial effects can be seen with relatively low tumor rad doses which are achievable without bone marrow transplantation." (*Id.*).

The fourth abstract published in 1990 ("Abstract # 66") involved the results of a ten-patient study using the ^{131}I-MB1 treatment. (*See* IDEC Ex. 8). The authors stated that the "major goal of this study was to define a maximum tolerated dose (MTD) [of ^{131}I-MB1] which did not require marrow transplantation support." (*Id.*). In two of two patients treated with a single, higher dose of radiation, myelosuppression limited further escalation. (*Id.*). However, the authors observed that "[t]reatment of 4 [patients] at a lower [ ] dose level has resulted in grade 2 toxicity in two, grade 0 in one, and grade 4 in one." [FN8] (*Id.*). The authors then summarized their findings, explaining that "durable tumor responses were seen including one apparent complete response, one partial response, one minor response, and one mixed response ... We conclude that the 40 cGy whole body dose is the MTD for single dose I-131 MB-1 [RIT] in this patient population and that there is evidence for therapeutic activity at this dose level." (*Id.*). Thus, in this study, the authors specifically set out to, and did (at least for this patient group), discover a dose of ^{131}I that was both effective at treating B-cell lymphoma and did not require ABMT.

FN8. The authors go on to explain that the patient experiencing grade 4 toxicity had marginal blood counts before treatment began. (*See* IDEC Ex. 8).

Finally, the same authors published a fifth abstract in 1990 ("Abstract # 1409") that summarized the results of an eleven-patient group treated with ^{131}I-MB1. (*See* IDEC Ex. 9). Like Abstract # 66, this abstract indicated that the "major aim was to define a maximum tolerated dose (MTD) [of ^{131}I-MB1] not requiring marrow transplant." (*Id.*). Again, the authors observed that two patients who were treated with higher levels of radiation (50 cGy) exhibited "dose-limiting myelosuppression," meaning that higher doses of radiation would have required ABMT. (*Id.*). However, like the study described in Abstract # 66, patients receiving lower doses of radiation achieved results without inhibiting myelosuppressive activity. Specifically the authors revealed that "[d]urable tumor responses were seen beginning at the 20 cGy WB dose level [ ] including one apparent complete response, one partial response, one near partial response and one mixed response." (*Id.*). Again, the authors arrived at the conclusion that a "40 cGy WB dose is likely to be the MTD for single dose 131-I MB-1 RIT in this [patient] population and there is evidence for therapeutic activity at and below this dose level." (*Id.*).

In November of 1992, Drs. Kaminski, Wahl, Miller and others published an article in the Journal of Oncology entitled "Imaging, Dosimetry, and Radioimmunotherapy With Iodine 131-Labeled Anti-CD37 Antibody in B-Cell Lymphoma" (the "1992 article"). (*See* IDEC Ex. 10 at 1696). This article discussed the findings of ^{131}I-MB1 treatment of twelve patients with B-cell lymphoma. (*Id.*). Once again, the authors noted that two patients who received a 50 cGy dose exhibited myelosuppressive activity that prevented further dose escalation. (*Id.*). However, other patients that received doses of 40 cGy and below were able to achieve tumor responses without the need for ABMT. (*Id.*). The authors concluded that ^{131}I-MB1 "can produce tumor responses at nonmarrow ablative [not requiring ABMT] RIT doses. Further studies that focus ... on this or other B-cell-reactive radiolabeled antibodies and on ameliorating the myelosuppression associated with the RIT-dosing approach used in this trial are warranted." (*Id.*). Finally, the authors explained in the 1992 article that "[w]ith these results in mind, we have begun studies with a different antibody, the anti-CD20 antibody, anti-B1 [the antibody that is claimed in the patents at issue] ... It is our hypothesis that this antibody will provide superior tumor targeting and thus result in greater and more durable tumor responses with less accompanying myelosuppression per [dose]." (*Id.* at 1710). Here, then, the authors

again expressed that tumor responses could be achieved with ^{131}I-labeled MB1 without necessitating ABMT and also stated their suggestion to others, and their own intentions, to experiment with the B1 antibody in place of the MB1 antibody.

C. The Prosecution History of the Patents at Issue

***4** On September 16, 1993, Drs. Kaminski, Wahl, Butchko and Glenn applied for the '721 patent, which was eventually granted and assigned to Coulter Pharmaceutical, Inc. (*See* IDEC Ex. 37 at 435273). The '721 patent became the "grandfather" patent upon which the '524, '365, and '537 patents were based. When filing their patent applications and during prosecution, the patentees made various disclosures of prior art references in the form of Information Disclosure Statements (IDS). None of the prior art references described above were ever listed in an IDS during the prosecution of any of the patents at issue.

The patentees did, however, provide a partial description of their ^{131}I-MB1 work in a section of the patent application entitled "Description of Related Art." This section consisted of one paragraph which reads in part:
Recently, we performed a study using the pan-B-cell antibody MB-1 labeled with [^{133}I]. MB-1 is an [ ] anti-CD37 monoclonal antibody, which binds to B cells ... In a study, twelve patients with refractory B cell lymphoma were evaluated for the biodistribution of ^{131}I-labeled MB-1, its imaging potential, toxicity, and therapeutic effect. Successful imaging of tumors has been achieved in all but one of our patients. Significant clinical responses have been documented, although only one complete response and one partial response were achieved at the dose levels employed. Also, severe myelosuppression precluded further dose escalation.

Patentees' Ex. A at 5:28-6:11. Also, the patentees cited to the 1992 article in the "Detailed Description of the Invention" section of the application and listed that article as reference 49 at the end of the application. However, the 1992 article was not cited to at any point during the patentees' description of the MB1 studies. (*See* Patentees' Ex. A at 5:28-6:11). Rather, it was referenced to describe relatively insignificant aspects of the B1 clinical protocol, such as how often human anti-mouse antibody responses were assessed in patients. (*See* Patentees' Ex. A at 30:9-30:12).

The references that the patentees did disclose via an IDS included various publications of their work with B1. Some of these references included a 1993 article in the New England Journal of Medicine (the "1993 article"), and an abstract published in September of 1992 ("Abstract # 57") that described the B1 protocol as including the administration of a radioimmunotherapeutic dose of ^{131}I-B1 "not expected to require marrow transplant support." (*See* IDEC Ex. 37 at 000472). Additionally, after the examiner rejected the claims of the '721 patent, the patentees disclosed another abstract ("Abstract # 144"), published in 1991, which did not describe any dose regimen or therapy, but rather a tumor imaging method. (*See id.* at 000654). Because their publication dates were less than one year before the '721 application was filed, the patentees were eventually able to "swear behind" the 1993 article and Abstract # 57. *See* 35 U.S.C. § 105(b). Also, after submitting an affidavit, the patentees were able to avoid the use of these two references under 35 U.S.C. § 102(a) because the references were not the "work of another." [FN9] *See In re Katz*, 687 F.2d 450 (CCPA 1982). In short, because of the publication dates and authors of the 1993 article and Abstract # 57, these references, which were actually disclosed via an IDS, could not be used as prior art against the patentees.

FN9. Significantly, Dr. Miller of IDEC was not an author of the 1993 article or Abstract # 57. Had he been, those references would have been useable by the examiner against the patentees as "work of another" because Dr. Miller is not a named inventor in any of the patents at issue.

***5** The '721 patent, as mentioned above, was the first patent to undergo prosecution. On May 10, 1994, the examiner issued an office action rejecting all pending claims. (*See* IDEC Ex. 37 at 000467). One of the grounds for rejection of the claims was the obviousness of the invention in light of two disclosed publications; one by Press and one by DeNardo.[FN10] (*Id.* at 000472). As the examiner explained:

FN10. The examiner also rejected the claims based on the 1993 article and Abstract # 57. However, as mentioned above, the patentees were able to swear behind these references, and thus the examiner's rejections on these grounds were withdrawn.

Press et al. disclose a method of immunotherapy of B cell lymphoma whereby imaging studies are first performed using MB-1 (anti-CD37) [labeled with] ^{131}I. Although Press et al. do not teach that the antibody which is administered is B1 ..., [because] B1 [is also] known to bind B cell lymphomas, it would be obvious to substitute [B1] for the MB-1 of Press et al. [Although] Press et al. do not teach radioimmunotherapy at doses such that bone marrow transplantation is not required ..., it would have been obvious to perform another dose escalation study as a routine experiment in order to determine the maximal amount of radioactivity that is possible without having to perform bone marrow transplantation.
IDEC Ex. 37 at 000473. The examiner also went on to explain that the pre-dosing step taught in the '721 patent was obvious because such a procedure was described in DeNardo et al. (*See id.* at 000473-74). Thus, the examiner held that the three primary aspects of the claimed invention (use of the B1 antibody, a dose of radiation that did not require ABMT, and pre-dosing with non-labeled antibodies) were obvious in light of the Press and DeNardo prior art references.

On November 10, 1994, the patentees responded to the examiner's rejection. The patentees asserted two arguments in response to the rejections based on Press and DeNardo. First, the patentees argued that Press did not make obvious the use of the B1 antibody. Specifically, they contended that Press had observed poor results using the 1F5 antibody (which is related to the B1 antibody) and, consequently, Press actually would teach away from the use of B1. (*See* IDEC Ex. 37 at 000592). Second, the patentees argued vigorously that it was not obvious in view of Press to discover a dose of radiation that did not require ABMT. Here, the patentees asserted that Press and DeNardo only taught "a radioactivity dose that requires [ABMT] support of the patient." *Id.* at 000593). Thus, the patentees argued, because the dose range in their invention *"does not require [ABMT]* ... the radiotherapeutic dosage range distinguishes the present invention from that disclosed by the combination of [Press and DeNardo]." *Id.* at 000592 (emphasis in original).

Upon receiving the patentees' response, the examiner issued another rejection of all pending claims on approximately February 6, 1995. This time, the examiner had Abstract # 144 (which involved the use of B1 specifically and was authored by the patentees) before him.[FN11] The examiner first noted that Abstract # 144 "did not disclose a dosage regimen for the treatment and imaging of patients with B cell lymphoma." *Id.* at 000608. However, the examiner then explained that "to a person of ordinary skill in the art, the same would have been obvious as a matter of routine experimentation in order to determine the maximal amount of radioactivity possible without having to perform bone marrow transplantation." *Id.* The examiner went on to note that another prior art reference, Abrams et al., also taught the pre-dosing method claimed in the invention. (*See id.* at 000608-9). The previous rejections based on Press and DeNardo were withdrawn as moot since the examiner could now rely on Abstract # 144 and Abrams for the same propositions. (*Id.* at 000609).

> FN11. Although Abstract # 144 was not disclosed to the PTO at the time the '721 application was filed, it was disclosed by the patentees in a subsequent IDS after the first rejection was issued.

***6** On August 25, 1995, the patentees responded to the second rejection of the claims. Here, the patentees focused almost exclusively on attacking the rejection based on Abstract # 144, primarily on the grounds that Abstract # 144 did not teach a dosage of radioactivity that did not require ABMT. The patentees stressed that Abstract # 144 only involved imaging of lymphomas and contained "no specific treatment step ... In fact, there is no disclosure at all with respect to the idea of administering a therapeutic dose to avoid a marrow transplant ... Therefore, the Abstract does not disclose or suggest the invention." (*Id.* at 000654-55). Finally, the patentees again emphasized that the "therapeutic dose of the present invention is limited to one which does not require [ABMT] to support the patient. Thus, the claimed radiotherapeutic dosage range, which is not taught or supported by Abstract # 144, clearly distinguishes the claimed invention from this reference." *Id.* at 000656. In sum, it appears that the patentees largely conceded that the use of B1 and pre-dosing were obvious in light of the prior art that was disclosed, but maintained that the non-ABMT dose was the point of novelty warranting issuance of the patent. The PTO apparently agreed with the patentees and allowed the claims in the '721 application to issue. (*See id.* at 000670).

In the prosecution of the '542 patent, the patentees again relied on the non-ABMT dose to overcome obviousness rejections. This time, the examiner relied on a combination of Abstract # 144 and Eary et al. As the examiner explained in the first rejection of the claims:

Eary et al. disclose the administration of a therapeutic dose of ^{131}I labeled anti-lymphoma monoclonal antibodies which resulted in complete remissions of B Cell lymphoma. The doses used were ... described as being "at the upper limit of marrow toxicity." Two of the three patients did not have myelosuppression severe enough to require infusion of bone marrow. Eary et al. do not teach the use of [B1] antibodies. [Abstract # 144] report[s] that the [B1] antibody, when labeled with ^{131}I provides advantageous results for radioimmunotherapeutic targeting of B cell lymphoma ... To a person of ordinary skill in the art, it would have been obvious to use the specific antibody taught by [Abstract # 144] in the composition of Eary et al.

IDEC Ex. 38 at 003744.

The patentees responded to the examiner's rejection using the same argument that overcame the rejections of the '721 claims. Specifically, the patentees asserted that
Even if [Abstract # 144 and Eary] were combined in the manner suggested by the Examiner, one would simply perform the experiments conducted by Eary using [the B1] antibody, but would still fail to achieve Applicant's claimed composition which is an amount effective for achieving remission of lymphoma without causing myelosuppression severe enough to require [ABMT].

***7** *Id.* at 003754. When the examiner was unpersuaded, the patentees amended their claims to specify a radiation dose range of 10 to 200 cGy to the whole body of the patient. (*See id.* at 003793). The patentees claimed that this narrowed dose range avoided Eary because the doses taught in Eary "are significantly higher than the operating range of Applicant's composition ... This maximal whole body dose [of 200 cGy] is critical to Applicant's invention, a composition which is effective against B-cell lymphoma and avoids [ABMT]." *Id.* at 003796.

On September 26, 1997, the Examiner again rejected the claims of the '542 patent application, this time relying on Abstract # 144, Eary and Buchsbaum. As the examiner explained, Buchsbaum et al "disclose a composition comprising a therapeutic dose [ ] of ^{131}I labeled [B1 antibody]. No bone marrow transplantation was necessary." *Id.* at 003778. However, the examiner also recognized that Buchsbaum did not disclose a dose that was effective in treating human lymphomas since Buchsbaum's experiments were directed at mice. (*See id.*).

The patentees filed a response on January 27, 1998. The patentees addressed the examiner's reliance on Buchsbaum by arguing that from that reference "one could not extrapolate to a human patient" and that Buchsbaum himself "recognized the difficulty of modifying the dosages in his protocol to treat humans for lymphoma." *Id.* at 003794-95. As to Eary and Abstract # 144, the patentees argued again that "Eary discloses a therapeutic dose [that is] significantly higher than the operating range of Applicant's composition which provides a maximum irradiation of 200 cGy to the whole body ... This maximal body dose is critical to Applicant's invention, a composition which is effective ... and avoids [ABMT]." *Id.* at 003796. After another rejection, the patentees vehemently argued that the non-ABMT-requiring dose was, in fact, a breakthrough in lymphoma treatment that deserved patent protection. The patentees stressed the fact that "the composition as claimed is effective for achieving remission of B-cell lymphoma in a human patient, yet does so without being myeloablative." *Id.* at 003892. The patentees then described this facet of the invention as "a groundbreaking alternative to known treatments [ ] in that it provides a precisely defined composition that is highly effective against disease yet does not cause myelosuppression of a level that [requires ABMT]." *Id.*

The examiner subsequently issued a notice of allowability, having been persuaded by the patentees' arguments. In his "reasons for allowance" the examiner explained that he found that "Buchsbaum and Eary do not disclose or suggest such compositions having an amount of radioactivity within the instantly claimed range [of 10 to 200 cGy]." [FN12] *Id.* at 003906. The examiner went on to describe the point of novelty that allowed the claims to issue:

> FN12. It is worthy to note at this point that the dose described in the MB1 prior art to be effective at treating B-cell lymphoma and avoiding ABMT was 40 cGy.

***8** Given the unexpected properties present in the instant claims, (i.e., that the instant composition has an amount of radioactivity that achieves remission of B-cell lymphoma while being less than the amount which causes myelosuppression severe enough to require [ABMT]), it would not have been obvious to one of ordinary skill in the art to modify the range of radioactivity [to] arrive at a composition which shows these specific unexpected properties. [I]t

appears that the instantly claimed range of radioactivity in the compositions shows evidence indicating such concentration is critical.
Id. at 003906. Thus, the examiner allowed the claims of the '542 patent because of the novelty of the specific dose range (10 to 200 cGy of radiation) and the result of that dose range (providing effective treatment of B-cell lymphoma while not necessitating ABMT).

The prosecution of the '365 and '537 patents proceeded in largely the same fashion. After the examiner in the '365 prosecution issued a rejection of the claims based on Press and other prior art references, the patentees amended the claims to include a non-ABMT limitation. *See* IDEC Ex. 39 at 000166). The patentees then argued that the new claims "now recite that the amount of radiolabeled antibody delivers a dose to the patient which is less than the amount which would cause myelosuppression sever enough to necessitate [ABMT]." *Id.* at 000172. The examiner subsequently allowed the claims of the '365 application to issue. (See id. at 000189). Finally, the patentees argued in the prosecution of the '537 patent that "all of the instant claims of the present continuing application reflect issued and/or allowed claims of grandparent [i.e., the '721 patent] and parent applications ..." IDEC Ex. 40 at 000864. The examiner thus did not reject any claims in the '537 application on the basis of prior art.

D. The Instant Motion

IDEC filed this motion for summary judgment arguing that there is no issue of material fact as to whether the patentees engaged in inequitable conduct before the PTO when prosecuting the patents at issue. Specifically, IDEC argues that the patentees intentionally withheld and concealed the prior art references related to the MB1 studies and that had any of these references been brought to the PTO's attention, the patents would never have issued. On September 5, 2003 defendants filed an opposition to IDEC's motion in which they argue that the MB1 prior art was not material and that, in any case, the patentees acted in good faith at all times before the PTO. IDEC subsequently filed a timely reply. The Court now turns to a discussion of IDEC's motion.

DISCUSSION

A. Legal Standard for Summary Judgment

"Under Rule 56(c), summary judgment is proper when the pleadings and discovery, read in the light most favorable to the nonmoving party, demonstrate that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Armstrong v. Burlington Northern R. Co.*, 139 F.3d 1277. 1278 (9th Cir.1998) (quoting *20th Century Ins. Co. v. Liberty Mut. Ins. Co.*, 965 F.2d 747, 750 (9th Cir.1992)); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A dispute is "genuine" when "the evidence presented is such that a jury applying that evidentiary standard could reasonably find for either the plaintiff or the defendant." *Anderson*, 477 U.S. at 255.

***9** Once the moving party meets the requirement of Rule 56, the burden shifts to the party resisting the motion, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256. It is not enough for the party opposing a properly supported motion for summary judgment to "rest on mere allegations or denials of his pleadings." *Id.* Genuine factual issues must exist that "can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Id.* at 250. To make such a showing, the nonmoving party must go beyond the pleadings to designate specific facts showing that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The requirement that a nonmoving party go beyond the pleadings is meant to further one of Rule 56's principal purposes, namely "to isolate and dispose of factually unsupported claims or defenses." *Id.* at 323-324. However, such evidence need not be in a form admissible at trial to avoid summary judgment. *Id.* at 325.

1. Legal Standard for Inequitable Conduct Before the PTO

A patent applicant must act with candor, good faith, and honesty when prosecuting a patent before the PTO. *See* 37 C.F.R. § 1.56(a); *Semiconductor Energy Lab. Co. v. Samsung Elec. Co.*, 204 F.3d 1368, 1373 (Fed.Cir.2000). Accordingly, any person before the PTO has a duty to disclose "all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a). This duty to disclose is "deemed to be satisfied if all information known to be material to patentability of any claim

issued in a patent was cited by the Office or submitted to the Office in [an IDS]." *Id.* The intentional breach of the duty to disclose constitutes inequitable conduct and results in the unenforceability of any patents so obtained. *See* LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n, 958 F.2d 1066, 1070 (Fed.Cir.1992).

In order for a party to prevail on a claim of inequitable conduct, it must prove the existence of two elements by clear and convincing evidence. First, the party must prove that the misrepresentation was material to the prosecution of the patent. Second, the party must also prove that the misrepresenting entity intended to deceive the PTO. *See* Li Second Family Ltd. P'ship v. Toshiba Corp., 231 F.3d 1373, 1379 (Fed.Cir.2000). Once a threshold showing of materiality and intent have been made, a district court must weigh the two elements and determine whether inequitable conduct occurred. *Id.* The more material the misrepresentations, the less evidence of intent to deceive is required for a finding of inequitable conduct. *Id.*

The Court is mindful that the grant of summary judgment involving a defense of inequitable conduct is a rare occurrence and should only be allowed with great caution. *See* Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1381 (Fed.Cir.2001) (quoting Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422, (Fed.Cir.1988)). However, the Federal Circuit has also recognized that "[a]lthough the premises of inequitable conduct require findings based on all the evidence, a procedure that may preclude summary determination, a motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." Abbott Laboratories v. TorPharm, Inc., 300 F.3d 1367, 1379 (Fed.Cir.2002) (quoting ATD Corp. v. Lydall, Inc., 159 F.3d 534, 547 (Fed.Cir.1998)).

B. Analysis

1. Whether the Patentees Fulfilled their Duty of Disclosure

***10** An applicant's duty of disclosure is described in 37 C.F.R. § 1.56(a) ("Rule 1.56(a)"). That rule initially defines the scope of the duty as requiring "disclos[ure] to the [PTO of] all information known to [the] individual to be material to patenability ..." 37 C.F.R. § 1.56(a). The rule goes on to explain the manner in which this duty can be discharged. Specifically, Rule 1.56(a) states that "[t]he duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the [PTO] or submitted to the [PTO] in the manner prescribed by § § 1.97(b)-(d) and 1.98." *Id.* 37 C.F.R. § § 1.97 and 1.98, in turn, describe the requisite features of an Information Disclosure Statement ("IDS"). Specifically, section 1.97 tackles matters of timing related to submitting an IDS, while section 1.98 addresses the content that an IDS must include. In sum, the combination of Rule 1.56(a) and sections 1.97 and 1.98 indicate that the duty of disclosure is satisfied when all material information is brought before the PTO in an IDS. Regarding the listing of publications (which are at issue here), section 1.98 states that "[e]ach publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date and place of publication." 37 C.F.R. § 1.98(b)(5).

The patentees first argue that there was no failure to disclose the MB1 prior art in the first place because they referenced the 1992 article, describing much of the MB1 studies, in their application. (*See* Patentees' Opp'n at 2-3). To support this argument, the patentees point to the Manual of Patent Examining Procedure ("MPEP") § 608.01(c). Section 608.01(c) states that a patent application must contain a "[d]escription of the related art including information disclosed [in IDSs] ... [explaining] the state of the prior art ..., including references to specific prior art or other information where appropriate." MPEP § 608.01(c). Thus, the patentees argue that citing a prior art publication as a reference in their description of the prior art can substitute for disclosure of that publication in an IDS.

The patentees' argument is both unsupported by law and contrary to common sense. Preliminarily, the Court notes that "[t]he MPEP does not have the force and effect of law; however, it is entitled to judicial notice as the agency's official interpretation of statutes or regulations, provided that it is not in conflict with the statutes or regulations." Refac Intern., Ltd. v. Lotus Development Corp. 81 F.3d 1576, 1584 n. 2 (Fed.Cir.1996).[FN13] Here, there is no indication that section 608.01(c) of the MPEP was meant to be an interpretation of 37 C.F.R. § 1.56(a) (which indicates that an applicant's duty of disclosure is satisfied if all information material to patentability

is provided in an IDS). Rather, this section of the MPEP explains what a "description of related art" should include, in *addition to* the mandated disclosures in the form of IDSs. Nowhere does section 608.01(c) indicate that citing a reference in the "description of related art" removes the need to bring that reference to the PTO's attention through an IDS.

> FN13. Indeed, the patentees themselves pointed out the non-binding effect of the MPEP at oral argument.

***11** The patentees' argument must also fail because their listing of the 1992 article as "reference 49" at the end of their application does not meet the requirements of 37 C.F.R. § 1.98. This reference to which the patentees ascribe so much importance reads in its entirety: "M.S. Kaminksi et al. J. Clin. Oncol., 10:1696 (1992)." In terms of discharging the patentees duty of disclosure, this cite listing is wholly inadequate. Section 1.98, as described above, mandates that a listing of a publication, in order to be considered by the examiner, "must be identified by publisher, author (if any), title, relevant pages of the publication, date and place of publication." 37 C.F.R. § 1.98(b)(5). Here, reference 49 lacks the title and relevant pages of the publication, among other items. Thus, even were the Court to agree that MPEP § 608.01(c) authorizes the manner of disclosure that the patentees argue, they nonetheless failed to abide by the clear requirements of section 1.98.

It is worthy to note at this juncture that the MPEP does shed light on the proper modes of disclosure available to an applicant when satisfying his or her duty of disclosure. This discussion is carried on not in section 608, however, as the patentees contend, but in section 609. MPEP § 609 explains that "[u]se of form PTO-1449, 'Information Disclosure Citation,' or PTO/SB/08A and 08B, 'Information Disclosure Statement,' is encouraged as a meas to provide the required list of [relevant patents, publications and other information required to be disclosed]." MPEP § 609. While clearly the preferred method of disclosure is through an Information Disclosure Citation ("IDC") or an IDS, section 609 does contemplate a list of citations submitted in other forms. [FN14]

> FN14. For example, MPEP § 609 states that if the required citations "are submitted on a list other than on a form PTO-1449 or PTO/SB/08A and 08B, the examiner may write 'all considered' and his or her initials to indicate that all citations have been considered." *See* IDEC Ex. 67 at 600-131.

Section 609 clearly mandates, however, that any such alternative submission cannot be done in the manner attempted by the patentees. MPEP § 609 states that

> The list of information complying with the identification requirements of 37 C.F.R. 1.98(b) may not be incorporated into the specification of the application in which it is being supplied, but must be submitted in a *separate paper.* A separate list is required so that it is easy to confirm that [an] applicant intends to submit an information disclosure statement and because it provides a readily available checklist for the examiner ...

MPEP § 609.03(a)(1) (emphasis added). Thus, the patentees cannot discharge their disclosure duties by citing to the 1992 article in the patent specification, and then listing that publication in a long list of references as part of (and not separate from) the patent application. For the 1992 article to have been properly placed before the examiner, and for the disclosure obligation to have been satisfied, it is clear that the article must have been listed in either (1) an IDC; (2) an IDS; or (3) a separate document that clearly indicated the intention that it be considered as an IDS.

Finally, the Court finds that allowing patent applicants to satisfy their duty of disclosure by listing a prior art reference as a citation at the end of their application would contravene the purpose of the IDS/IDC requirements. As evidenced by MPEP § 609, the purpose of mandating the use of these particular forms is to provide the examiner with a uniform system of disclosure, such that he or she knows exactly which references should be examined during the prosecution. (*See* MPEP § 609 ("The forms will enable applicants to comply with the requirements to list each item of information being submitted and to provide the [PTO] with a uniform listing of citations and with a ready way to indicate that the information has been considered.")). The list of references at the end of the patent application, however, necessarily includes additional citations to background material and other information not relevant to patentability. In fact, as described in detail below, the patentees' "disclosure" of the 1992 article as a citation was done in such a way as to imply that it was irrelevant.[FN15] Thus, the Court rejects the patentees' argument that their duty to disclose the MB1 prior art publications was satisfied through their citation to the 1992 article and its listing as a

reference at the end of their applications.

> FN15. As noted above, for example, the patentees did not cite to the 1992 article (reference 49) when describing the MB1 studies in the "description of related art." Thus, the examiner would not have any idea that the 1992 article involved that work.

2. Materiality of the Withheld Prior Art References

***12** Material withheld information, the first element in an inequitable conduct analysis, is defined as "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed.Cir.2003). 37 C.F.R. § 1.56(b) specifically indicates the criteria for determining what information is material to the examiner:

Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b). The Federal Circuit has been clear that information can be deemed material under this standard irrespective of whether it is ultimately found to invalidate the claims of the patent. *Bristol-Myers*, 326 F.3d at 1234. Finally, it is worthy to note that "[w]hen weighing whether uncited prior art is more material than that before the examiner, a trial court considers similarities and differences between the prior art and the claims of the patent." *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1441 (Fed.Cir.1991).

The patentees use a multitude of arguments in an attempt to persuade the Court that the withheld MB1 prior art is not "material" to the claims of the patents at issue. The Court will address in turn each of the patentees' arguments on this front.

First, the patentees argue that the undisclosed MB1 prior art publications contain no material information because it was already known in the art that non-myeloablative doses of radiation could have an effect on tumors. (*See* Patentees' Opp'n at 13). While this proposition may be true as a general matter, it hardly warrants the conclusion that the MB1 prior art contains no material information related to the prosecution of the patents at issue. Initially, the MB1 publications themselves distinguish what was already understood regarding the effect of non-myeloablative doses on lymphomas. For example, the 1992 article distinguishes the single whole body dose method used in the MB1 study (and claimed in the patents at issue) from previous work involving smaller, fractionated doses.[FN16] (*See* IDEC Ex. 10 at 032784).

> FN16. The authors of the 1992 article (who included the patentees) explicitly distinguished their work involving specific whole body dose ranges from Press, DeNardo and Goldenberg. (*See* IDEC Ex. 10 at 032795).

Furthermore, the point of novelty that the PTO found to warrant patent protection was not the general concept that radioactive doses could have effects on tumors without requiring ABMT support. Rather, the novel part of the invention was the disclosure of the specific dosage range (10 to 200 cGy) that could provide effective treatment of human lymphoma without necessitating ABMT. As the patentees argued time and time again before the PTO, no prior art (at least no prior art before the PTO) had disclosed such a dosage range. The discovery of such a dosage range, however, was not only the explicit goal of the MB1 studies, it was proclaimed to have been realized in at least two of the publications resulting from that work. (*See, e.g.* IDEC Ex. 9 (Abstract # 1409) (explaining that "[t]he major aim was to define a maximum tolerated dose (MTD) not requiring marrow transplant support" and finding that "a 40 cGy dose level is likely to be the MTD for single dose 131-I MB1 RIT in this [patient] population and there is evidence for therapeutic activity as and below this dose level."); IDEC Ex. 10 (the 1992 article) (stating that the "study was undertaken to evaluate the tumor-targeting, toxicity, and therapeutic potential of [MB1] labeled with [^{131}I] given in a nonmarrow ablative dose range in B-cell lymphoma patients" and that "^{131}I-MB-1 RIT in this dose range can have definite antitumor effects.")). Thus, the patentees' argument that the MB1 prior art references contain no material information must clearly fail. True, it was well known in the art that non-myeloablative doses of radiation could *effect*

tumors. What was not known, and which is why the PTO allowed the claims to issue in the first place, was the specific dosage range at which human lymphomas could be treated without requiring ABMT support; a range disclosed in the MB1 publications.

***13** Patentees' second argument that the concealed MB1 prior art is not material is that the MB1 publications address MB1, not B1 antibodies. (*See* Patentees' Opp'n. at 14). Here, the patentees' miss the pertinent aspect of the MB1 studies. They appear to argue implicitly that to be material, a prior art reference must contain nearly every limitation of the claims at issue. The general standard for material prior art, however, is that which a reasonable examiner would be likely to consider important. Thus, the mere fact that the MB1 studies involved a different pan B-cell antibody does not, by itself, indicate that those studies are immaterial to patentability. To the contrary, the examiner of the '721 application specifically noted that it was obvious for one skilled in the art to experiment between different pan B-cell antibodies, such as MB1 and B1. (*See* IDEC Ex. 37 at 000473 ("Since B1 [and other pan B-cell antibodies] are all known to bind B cell lymphomas, it would be obvious to substitute one of them for the MB-1 [antibody].")).

The obviousness of substituting B1 for MB1 need not even be a reality, however, to defeat the patentees' argument. This is because one of the prior art publications not disclosed to the PTO expressly suggests to others, and then states that it is the intention of the authors, to conduct the same MB1 experiments using other pan B-cell antibodies, including B1 specifically. (*See* IDEC Ex. 10 at 1696 ("Further studies with this or other B-cell-reactive radiolabeled antibodies and on myelosuppression associated with the RIT-dosing approach used in this trial are warranted."); *id.* at 1710 ("With these results in mind, we have begun studies with a different antibody, the anti-CD20 antibody, anti-B1.")). Therefore, the fact that the MB1 publications do not deal expressly with the B1 antibody is of no consequence to their materiality. Due to the fact that the examiner thought it obvious to substitute antibodies, and one of the prior art references explicitly suggests this, the dosage ranges disclosed in the MB1 publications remain extremely relevant to the claims of the patents at issue.

The third argument advanced by the patentees regarding materiality of the MB1 prior art is that the undisclosed publications actually teach away from the patented invention. Specifically, the patentees argue that the MB1 study "did not report successful treatments" and that the results "would indicate to one of ordinary skill in the art that effective, low-dose, nonmyelosuppressive radioimmunotherapy was not yet achievable." (*See* Patentees' Opp'n. at 14-15). Of course, the conclusions of every one of the undisclosed prior art references is in direct contravention to the patentees' assertion. It is true that the 1992 article concluded that the "responses [in that MB1 study] were of short duration and did not exceed 6 months." IDEC Ex. 10 at 1709. However, the authors of the publications, who include the patentees, clearly felt that the MB1 experiments were successful. For example, Abstract # 1409 stated that "[d]urable tumor responses were seen beginning at the 20 cGy WB dose level" and Abstract # 1051 concluded that "131-I MB-1 ... has significant anti-tumor activity in [patients] with large tumor burdens at nonmyelosuppressive doses and at doses below those requiring bone marrow transplant support ..." (IDEC Exs. 6 and 9). "Durable tumor responses" and "significant anti-tumor activity" are not phrases one would expect to be used when indicating that radiation doses at these levels are a lost cause.

***14** Additionally, the fact that some tumor remissions in the MB1 studies were not permanent does not mean that the accompanying publications "teach away" from the patented invention. In actuality, it was the MB1 studies themselves that led the patentees to experiment with B1 and make the discovery that was eventually patented. (*See id.* at 1710 (indicating that the authors (who are also named inventors of the patents at issue) had begun to experiment with B1 in light of the MB1 results)). Moreover, there is no claim limitation in any of the patents at issue which requires that the treatment produce results that are durable up to a certain time period. This Court's Order construing the claims of the patents at issue support this conclusion in that the terms "radioimmunotherapeutically effective amount" and "effective for achieving remission of B-cell lymphoma" were construed to mean "an amount that specifically results in a benefit or provides a measurable influence for the benefit of a patient ..." (*See Markman* Order at 25). Thus, the specific duration of the tumor responses in the MB1 studies is not indicative of the materiality of those studies to the patents at issue.

As their fourth argument that the MB1 prior art is not material, the patentees suggest that the examiners did not think that similar MB1 disclosures were material. (*See* Patentees' Opp'n. at 15). To support their

argument the patentees' point out that prior art references by Goldenberg and Parker, which dealt with non-myeloablative RIT doses, were before the examiners but did not result in any rejections. (*Id.*). This reasoning is unpersuasive for a number of reasons. First, the fact that the examiners did not rely on the Goldenberg and Parker references does not indicate that the examiner thought any MB1 prior art was immaterial. What is more likely is that the examiners did not feel required to rely on these references because other references were before them upon which they could also base their rejections. Second, the patentees themselves, in the undisclosed 1992 article, distinguish the search for a whole body, single, non-myeloablative dose (the goal of the MB1 studies and the novel portion of the claimed invention) from the work of Goldenberg. (*See* IDEC Ex. 10 at 1708 (distinguishing the patentees' MB1 work from the *fractionated* dosage approach used by DeNardo and Goldenberg)). As to the Parker reference, that work dealt with anti-idiotype antibodies and not the pan B-cell antibodies (such as MB1 and B1) which are involved in the invention. Finally, the Court notes that the Parker and Goldenberg did not reveal a dosage range for effectively treating human lymphomas without ABMT support. Only the withheld MB1 publications and the patented invention make such a disclosure. Thus, the fact that the examiners did not rely on the work of Parker or Goldenberg has little bearing on the materiality of the MB1 prior art.

***15** Fifth, the patentees assert that there were important differences between the B1 and MB1 clinical protocols that militate toward a finding that the MB1 studies are not material to the patentability of the invention. (*See* Patentees' Opp'n. at 15-16). Patentees' argument on this score fails for the same reason that their second argument fails; namely, that the MB1 prior art need not be identical to the patented invention to be highly material. The patentees' argue that the MB1 protocol differs from the B1 protocol in that (1) the B1 protocol called for the use of the B1, not MB1 antibody; and (2) the B1 protocol used pre-dosing, not co-dosing with "cold" antibodies. (*Id.* at 16).

Both of these aspects (substituting B1 for MB1 and employing pre-dosing) were found to be obvious by the examiners. (*See,* e.g., IDEC Ex. 37 at 000473 ("Since B1 [and other pan B-cell antibodies] are all known to bind B cell lymphomas, it would be obvious to substitute one of them for the MB-1 [antibody]."); *id.* at 000608 ("[T]o a person of ordinary skill in the art, preloding is a well-known and useful tool for both radioimmunodetection and radioimmunotherapy. For example, Abrams et al. teach the administration of blocking [or cold] antibodies prior to the administration of radiolabeled [or hot] antibodies ...")). Thus, the fact that these differences exist between the undisclosed MB1 prior art and the patented invention does not have any significant bearing on their materiality. Moreover, the patentees themselves recognized the substantial similarities between the B1 and MB1 protocols during discussions between them, leading up to the start of clinical trials with B1. (*See* IDEC Exs. 15, 17, 19). In any event, it is beyond dispute that the MB1 prior art and the B1 invention do share the most important of aspects: the point of novelty (the effective, yet non-myeloablative dose range) of the patents at issue.

Finally, the patentees contend that the MB1 prior art is "merely cumulative to or less material than other references before the examiner." Patentees' Opp'n at 16. Here, the patentees allege that the Press, Buchsbaum and Eary references were more material, and thus make cumulative, the undisclosed MB1 prior art. (*See id.* at 17). It is amusing that the patentees claim that the PTO itself "acknowledged ... that Buchsbaum and Eary were the most material references ..." *Id.* Of course, that fact would be more important had the patentees decided to disclose the MB1 references as they were required to do. As it stands, however, all that can be said is that the PTO thought Buchsbaum and Eary were the most material of the references that were actually before the examiners. The fact remains, moreover, that the patentees clearly overcame the rejections based on Buchsbaum and Eary by arguing that those references did not disclose a dosage range that was both effective in treating human lymphomas and did not require ABMT support. The discovery of such a dosage range, albeit with the MB1, not B1, antibody, was the explicit goal of the MB1 studies. Lastly, two of the publications resulting from the MB1 studies (Abstract # 1409 and the 1992 article) actually disclose the finding of such a dosage (40 cGy) that is within the dosage range claimed in the patents at issue (10 to 200 cGy).

***16** In short, the patentees' arguments regarding the immateriality of the MB1 prior art are without merit. Patentees, although making every attempt to disparage the importance of the MB1 prior art, cannot escape the fact that it discloses the very point of novelty that allowed their claims to issue. In other words, as the patentees argued time and time again with the PTO, no other prior art had disclosed a RIT

dosage range that was both effective in treating human lymphomas and did not require ABMT. This alleged point of novelty was clearly what enabled the patentees to overcome obviousness rejections set forth by the examiners. Thus, the fact that the undisclosed MB1 prior art absolutely and unequivocally undermines the most important argument asserted by the patentees to the PTO makes those references incredibly material.

3. Intent to Deceive on the Part of the Patentees

As an initial matter, the Court notes that due to the highly material nature of the withheld MB1 prior art, less evidence of deceptive intent is required for a finding of inequitable conduct. *See* Li Second Family, 231 F.3d at 1379. Nonetheless, the Court does not take lightly the moving party's burden on this matter. To prove the element of intent, the moving party must show that "[t]he omission [was] made with the specific intent to mislead, not merely from carelessness in the performance of a duty." *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1259 (Fed.Cir.2000). Moreover, a finding of materiality, no matter how great, does not lead to a presumption of intent. Rather, intent is a separate element of inequitable conduct that must be separately established. *See* *Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1567 (Fed.Cir.1988), cert. denied, 488 U.S. 850, 109 S.Ct. 132, 102 L.Ed.2d 104 (1988) ("Materiality does not presume intent, which is a separate and essential component of inequitable conduct."); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed.Cir.1991).

In order for an intent to deceive to be found, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require [such] a finding." *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1189 (9th Cir.1993) (quoting *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.* 863 F.2d 867, 876 (Fed.Cir.1988)). However, the Federal Circuit has recognized that this element "need not, and rarely can be, proven by direct evidence." *Merk & Co. v. Danbury Pharmaceutical, Inc.*, 873 F.2d 1418, 1422 (Fed.Cir.1989). Thus, " 'smoking gun' evidence is not required in order to establish an intent to deceive" and "this element ... must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct." *Paragon*, 984 F.2d at 1189-90.

The patentees present what amounts to three arguments that they claim show that there is no intent to deceive. As discussed below, their first argument is based on conclusory statements in the declarations of two of the named inventors and the other to two arguments actually support a finding of deceptive intent. Moreover, the overwhelming weight of any reasonable inferences that can be drawn from the evidence and circumstances surrounding the prosecution of the patents at issue also support a finding of deceptive intent.

***17** Patentees' first argument supporting their claim that their concealment of the MB1 prior art was in good faith is that both Drs. Kaminski and Wahl have presented declarations stating that they believed that their actions were in compliance with their disclosure duties before the PTO.[FN17] (*See* Kaminski Decl at 2; Wahl Decl. at 1). After reciting their opinions regarding whether they complied with their disclosure obligations, Drs. Kaminski and Wahl state that it was never their intention to "deceive the [PTO] into granting us a patent." (*See* Kaminski Decl. at ¶ 20; Wahl Decl. at ¶ 21). Although the declarations of Drs. Kaminski and Wahl clearly constitute evidence of their good faith, they are not entitled to great weight in this situation. As the Federal Circuit has explained, a mere denial of an intent to deceive is not sufficient where a patentee faces a high level of materiality and proof that he or she knows or should have known of that materiality. *LaBounty*, 958 F.2d at 1076; *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed.Cir.1997). Here, as discussed above, the withheld MB1 prior art is unquestionably material. Moreover, there is ample evidence, set forth more fully below, that the patentees knew of that materiality, not the least of which is that they were the *authors* of the withheld publications and had explicitly stated their intentions to conduct the B1 studies *based upon* their efforts with MB1. (*See* IDEC Ex. 10 at 1710). As a result, the mere assertions by the patentees that they did not intend to deceive the PTO when they withheld the MB1 prior art cannot not, by themselves, carry the day.

FN17. IDEC has filed, together with their reply to the patentees' objections, a motion to strike the declarations by Kaminski and Wahl. Because the Court finds that consideration of these declarations does not affect the outcome of this motion for summary judgment, the Court DENIES AS

MOOT IDEC's motion to strike.

The patentees' second argument that they had no deceptive intent in withholding the MB1 prior art from the PTO is that they actually disclosed the MB1 studies in the "description of related art." (*See* Patentees' Opp'n. at 10). Were the Court to look no further than the fact that the MB1 studies are discussed in the patent applications, the patentees would surely prevail on the issue of deceptive intent in summary judgment. However, a closer examination of what was included in this artful "disclosure" reveals that the statement is actually evidence that supports a finding of culpability on the part of the patentees.

The manner in which the MB1 work was brought before the PTO cannot be described as anything short of misleading and inaccurate. First, the description of the MB1 studies in the patent application mentions only "work" that was done with MB1, and makes no mention whatsoever of any publications (which would be prior art that could be used against the patentees) resulting from this work. Thus, an examiner would be led to believe that the MB1 studies were merely a failed trial leading to the B1 studies that resulted in the invention. Second, the patentees refer to the MB1 studies as their own work, failing to mention that Dr. Miller of IDEC was also involved in (and in large part spearheaded) the studies and the resulting publications. This is significant because had the PTO known that a non-named inventor was involved, the MB1 studies could potentially constitute prior art as the "work of another." *See* 35 U.S.C. § 102(b).

***18** Most importantly, the description of the MB1 studies is entirely silent as to the most central feature, and, indeed the explicit goal, of that work: the discovery of an effective, non-ABMT dose of radiation. Indeed, the patentees deceptively imply that such a dose was not discovered at all because "severe myelosuppression precluded further dose escalation." (*See* IDEC Ex. 1 at 3). To the contrary, however, the 1992 article states that such preclusive myelosuppression occurred in only *two* of twelve patients, and that other patients achieved tumor responses at doses below those inducing myelosuppression. (*See* IDEC Ex. 10 at 1709). To imply that the MB1 studies failed because of problems with myelosuppression when in fact only a small fraction of the patients treated had such difficulties is plainly misleading. Every one of the undisclosed prior art publications concludes, in one way or another, that the MB1 studies demonstrate that a non-ABMT dose range can produce effective results in B-cell lymphomas. The patentees' description of the MB1 work, however, not only excludes those conclusions, it artfully suggests that no such dosage range was found. This, coupled with the fact that the primary argument throughout prosecution was that the novel part of the invention was the discovery of an effective, non-myeloablative dosage range, is evidence of deceptive, not honest, intent.[FN18]

> FN18. The patentees cite to Federal Circuit cases in which courts found no deceptive intent because otherwise withheld prior art was described in various portions of the patent applications. (*See* Patentees' Opp'n. at 10, citing *Speedplay*, 211 F.3d 1245; *Upjohn Co. v. MQVA Pharm. Corp.*, 225 F.3d 1306 (Fed.Cir.2000); and *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed.Cir.2000)). In none of these cases, however, did the court indicate that the descriptions of the prior art were anything less than genuine and honest. Here, however, the manner of "disclosure" was deceptive and misleading in itself.

The patentees' third argument regarding good faith is predicated on their citation to the 1992 article in the patent application and their listing of that article as reference 49 at the end of the application. Similar to their description of the MB1 prior art, however, this fact, when examined more closely but in the patentees' favor, actually supports, and is evidence in favor of, a finding of deceptive intent. Numerous aspects of the 1992 article's presentation supply evidence that the patentees' intent was culpable. First, the patentees did not cite to the 1992 article at the end of their description of the MB1 work despite the fact that the 1992 article was entirely based on and summarized the MB1 studies. This was done in contrast to every other description of previous studies and work in the application, all of which were followed by a citation to the publications arising therefrom. (*See* IDEC Ex. 1 at 1-5). Second, when the patentees did cite to the 1992 article, it was in relation to non-material matters that had nothing to do with patentability. [FN19] Never once was there any indication that the 1992 article involved the use of ^{131}I-MB1 RIT and that the study was done in order to determine an effective dose not requiring ABMT support. Rather, the manner in which the 1992 article was cited to did nothing less than infer that it was not relevant prior art at all. Finally, when listed as reference 49, the 1992 article's title was omitted,

which would have indicated its true nature as a publication of the inaccurately portrayed MB1 work. Thus, while the plain fact that the 1992 article was cited to in the patent applications would be evidence of good faith, the deceptive and misleading manner in which it was portrayed and cited to, even if viewed in a light favorable to the patentees, reveals evidence of an intent to deceive the PTO by concealing this and the other MB1 publications.

> FN19. The 1992 article was cited to for its description of "spot gamma camera scans," how tumor imaging sensitivity was obtained, and how human anti-mouse antibody responses were assessed. (*See* IDEC Ex. 1 at 14-15).

***19** The patentees, at oral argument, asserted that the Federal Circuit's decision in *Fiskars* precludes a finding of deceptive intent due to the citation to the 1992 article, regardless of how that prior art was presented. In *Fiskars,* a patentee was charged with inequitable conduct for not properly disclosing a device similar to his invention that he had seen at a trade show. *See* Fiskars Inc. v. Hunt Mfg. Co., 221 F.3d 1318 (Fed.Cir.2000). The patentee had listed a brochure for the device in a Form 1449(IDC), but the examiner had drawn a line through it and not considered that reference during prosecution. Id. at 1327. The defendant nonetheless argued that the patentee should have further informed the PTO of the device's relevance. *Id.* In rejecting the defendant's contentions, the Federal Circuit first noted that "[t]he prosecution history shows a brochure describing the [device] listed on PTO Form 1449[ ] and submitted to the PTO." *Id.* The court went on to conclude that "[a]n applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner ... An applicant is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for inequitable conduct." *Id.* The patentees argue, accordingly, that since they cited to the 1992 article and listed it at the end of the patent application, *Fiskars'* holding is applicable.

The Court cannot accept the patentees' contention that *Fiskars* is controlling in this case. First, the patentee in *Fiskars* properly brought the prior art reference before the PTO, through the use of Form 1449 (an IDC). As discussed above, this form, in addition to the IDS, are the two methods that the MPEP suggests to bring important information to the PTO's attention. Thus, the patentee in *Fiskars* had done everything required of him to bring the prior art before the PTO. This was clearly indicative of good faith. Here, although the patentees brought many other less material prior art references to the PTO's attention through IDC forms, they failed to list the 1992 article, or any of the other MB1 publications, even once in any of those forms. Rather, they decided to bury the 1992 article in the middle of a list of ninety-four references at the end of their applications. The PTO has explicitly rejected such attempts to discharge one's disclosure obligations. *See* MPEP § 609.03(a)(1) (requiring disclosure in an IDS, IDC or a *separate document* intended to serve as an IDS). Moreover, as previously mentioned, the patentees deceptively inferred from their citations to that publication, that it was wholly irrelevant to patentability.

The second reason that the *Fiskars* decision cannot avail the patentees here is that the Federal Circuit explicitly stated that decision did not apply to a situation such as this, involving improper disclosure. Here, unlike in *Fiskars,* the patentees did not produce the prior art publication in accordance with 37 C.F.R. § § 1.97 and 1.98. As outlined above, section 1.98(b)(5) requires that a publication reference include the title as well as the relevant page numbers, neither of which is present in the patentees' "reference 49." In *Fiskars,* the court stated the following in a footnote:

***20** MPEP 609 directs an examiner to line through, and not consider, a prior art reference when the requirements of 37 C.F.R. § 1.97 or § 1.98 have not been satisfied. Hunt has not argued that Fiskars failed to satisfy any of these requirements, and the examiner gave no reason for the action. Therefore, we do not address the status of a reference that was submitted to the PTO without satisfying 37 C.F.R. § 1.97 and § 1.98.

Fiskars, 221 F.3d at 1327, n. 2. Thus, the *Fiskars* court explicitly warned that it was not deciding a situation, as here, involving an inadequate disclosure that the examiner would never have reason to look at in the first place. For these reasons, the Court finds that *Fiskars* does not control, nor does it bear on, the instant case.

The other evidence and circumstances of this case, although construed in favor of the patentees, can only lead to an inference that the patentees knew of the materiality of the MB1 publications and intentionally withheld their contents from the PTO.

An intent to deceive is properly inferred when "a

patent applicant knew, or should have known, that withheld information could be material to the PTO's consideration of the patent application." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.* 326 F.3d 1226, 1239 (Fed.Cir.2003) (citing *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 at 1375-76 (Fed.Cir.2001)). In this case, there is ample evidence that the patentees knew of the materiality of the withheld MB1 prior art. First and foremost, the patentees not only conducted the MB1 studies, but also authored the publications arising therefrom. Thus, it was the patentees themselves that stated that the "[t]he major aim [of the MB1 studies] was to define a maximum tolerated dose (MTD) not requiring marrow transplant support" and that "a 40 cGy [whole body] dose is likely to be the MTD for single dose 131-I MB-1 RIT ... and there is evidence for therapeutic activity at an below this dose level." (*See* IDEC Ex. 9 (Abstract # 1409)). When considering that the primary argument for patentability, which was eventually the reason the claims issued, was that the invention was novel because of its disclosure of an effective, single, whole body dose that did not require ABMT, the only possible inference is that the patentees knew of the substantial materiality inherent in the MB1 prior art.

During discussions and development of the B1 clinical protocol, the patentees also made statements indicating that they thought the MB1 studies were similar to those using B1 that led to the invention. For example, in a letter to a Dr. Kortright at Coulter regarding the development of the B1 protocol, Dr. Kaminski explained that one of the enclosed protocols "deals with the use of ^{131}I-labeled MB-1 antibody." IDEC Ex. 14. The letter went on to state that the MB1 protocol "more closely reflects the type of study we intend to perform [with B1] and thus it represents a prototype which could be easily adapted such that B1 could be substituted for MB-1." *Id.* Apparently, Dr. Kaminski was correct since a comparison of the B1 and MB1 protocols reveals very few discrepancies beyond the substitution of "B1" where "MB1" appeared before. (*See* IDEC Ex. 13 with IDEC Ex. 29). The contents of an amended version of the B1 protocol sent to the FDA by Dr. Butchko in 1990 are also insightful. In that amended protocol, the patentees outline their chosen dose escalation scheme for ^{131}I-B1. Afterwards, the protocol states that "[t]he above starting dose was chosen because of our prior experience in a ^{131}I-MB-1 phase 1 study indicating a low likelihood of unacceptable toxicity at that level." IDEC Ex. 23 at 10. Again the previous writings and actions of the patentees provide clear evidence that they were more than aware of the materiality of the MB1 prior art.

***21** In *Baxter Intern. Inc. v. McGaw, Inc.*, an inventor had made analogous statements admitting materiality in a pre-litigation memorandum. There, the inventor had stated that the "Volts access site cap [a part of the invention at issue] was similar to the Borla Device [the undisclosed prior art]." *Baxter*, 149 F.3d 1321, 1329 (Fed.Cir.1998). The Federal Circuit held that the patent-holder was "stuck with the statements and actions of [the inventor]." *Id.* at 1330. The court concluded that the withheld prior art "was clearly relevant and the inventors were clearly aware of its existence. Moreover, given the degree to which the patented inventions were based upon the [withheld prior art], an inference that the inventors were aware of its importance is justified." *Id.* Here, the patentees have likewise admitted, in pre-litigation documents, the similarity between the MB1 work and the B1 invention. Although the Court now determines the existence of inequitable conduct on summary judgment, the evidence and circumstances described above can support no inference other than that the patentees intended to deceive the PTO by not disclosing the prior art references that they authored and by clearly misrepresenting the MB1 work in their applications.

In a situation such as this, where the concealed prior art is undoubtedly material and there are documents and facts indicating that the patentees were aware of that materiality, the Federal Circuit has stated that an inference of deceptive intent will most likely be proper. In *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, the court reaffirmed that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead." *LaBounty*, 958 F.2d 1066, 1076 (Fed.Cir.1992) (citing *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1416 (Fed.Cir.1987)). The court went on to explain that a "mere denial of intent to mislead [ ] will not suffice in such circumstances. *Id.* The evidence in this case, even if viewed in the patentees' favor, establishes that the concealed MB1 publications are clearly material and that the patentees were aware of this materiality. Thus, under the circumstances of this case, and in light of the evidence presented, the Court finds that it is proper to draw an inference that the patentees did intentionally deceive the PTO when they concealed the importance of and failed to disclose various MB1 prior art references.

Beyond any inferences that may be properly drawn, however, the Court also finds that the manner in which the MB1 studies and the 1992 article were placed before the PTO constitutes affirmative evidence of an intent to deceive. In *Paragon,* the Federal Circuit upheld a district court's grant of summary judgment where the applicant had not only withheld certain information, but had deceptively led the PTO astray in his communications. The applicant attempted to argue that "intent to mislead may not be 'presumed' from the mere failure to disclose known highly material information." Paragon, 984 F.2d at 1191. The Federal Circuit countered, stating that this "trusim does not apply here. The inference [of deceptive intent] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts." *Id.*

***22** Here, as in *Paragon,* there is clear evidence of deceptive intent from the character of the patentees "disclosures" to the PTO, in addition to the withholding of the prior art publications. As noted above, the patentees provided a disingenuous and wholly incomplete description of the MB1 work in their application. Their artful description fails to mention, and tends to imply the non-existence of, the following facts: (1) the existence of any publications that resulted from the MB1 work; (2) that there were other, non-named inventors that participated in that work; (3) that the explicit goal of that work was to find a non-myeloablative dose that was therapeutically effective; and (4) that the conclusions reached in the resulting publications stated that such a non-myeloablative dose had been discovered. Even if viewed in the patentees' favor, the blatant omissions and misleading implications of this "description" of the MB1 prior art must weigh in favor of finding culpable intent.

Moreover, the Court finds that there is also evidence of deceptive intent in the manner in which the 1992 article was "disclosed." Here, the patentees' actions infer culpable intent in that they (1) failed to cite to that reference when describing the MB1 studies, despite the fact that the 1992 article was entirely based on and summarized those studies (thus inferring to an examiner that no such publications existed); (2) explicitly cited to that reference only for matters that were clearly immaterial to patentability; and (3) redacted the title of the article when listing it as a reference, which would have revealed that publication's true contents. Thus, as in *Paragon,* the patentees' own actions and submissions before the PTO constitute evidence of deceptive intent.

In sum, the Court finds that even after all the evidence is viewed in a light most favorable to the patentees, and all reasonable inferences are drawn in their favor, the conclusion is inescapable that inequitable conduct and deceit permeated the prosecution of the patents at issue. Despite the patentees' arguments to the contrary, the concealed MB1 prior art is extremely material, as it unequivocally discloses the precise point of novelty stressed by the patentees and ultimately accepted by the examiners. As to the intent of the patentees, the only evidence that does not clearly support their culpability, even if viewed in their favor, is their own self-serving declarations. In light of the high degree of materiality of the undisclosed prior art, the fact that the patentees authored those publications, and their statements indicating knowledge that the MB1 studies were pertinent to the B1 work, the conclusory statements by the patentees cannot avoid a grant of summary judgment regarding inequitable conduct.[FN20]

FN20. The Court has remained aware that a grant of summary judgment involving a charge of inequitable conduct is a rare occurrence. Nonetheless, the facts and evidence in this case are such that the grant of IDEC's motion is proper. In the course of adjudicating the instant motion, the Court has received and meticulously reviewed thousands of pages of documents. These documents include the complete prosecution history of each of the patents at issue, correspondence between the patentees and others while the MB1 and B1 studies were on-going, the declarations of Drs. Kaminski and Wahl, among others, as well as the MB1 publications and other prior art references. Moreover, the Court conducted a hearing on this matter allowing both parties to raise additional matters and facts pertinent to this motion. It is also noteworthy that substantive discovery has all but concluded in this litigation. The Court, therefore, is satisfied that a trial would do little to add to the factual background and circumstances of this matter and finds summary judgment appropriate.

CONCLUSION

Based on the foregoing, the Court GRANTS IDEC's

motion for summary judgment that the '721, '542, '365 and '537 patents are unenforceable due to inequitable conduct before the PTO. Furthermore, the Court DENIES AS MOOT IDEC'S motion to strike the declarations of Drs. Kaminski and Wahl.

***23** IT IS SO ORDERED.

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